20 May 1999

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To: See Distribution List below

Subj: NEED TO AMEND FDA MODERNIZATION ACT OF 1997 SECTION 503A and MOU and
NEED TO CURTAIL FDA BLATANT ABUSE OF POWER

99 MAY 27 A9:51

Refs: (1) FDA Docket No. 98N-1265
(2) FDA Modernization Act of 1997, Section 503A governing the practice of pharmacy compounding
(3) FDA Memorandum of Understanding (MOU) that would limit the practice and interstate distribution of compounded drugs and nutrients

The FDA approves the sale of dangerous prescription drugs that kill over 400K people a year, and allows use of the poisonous heavy metal mercury (Hg) in "silver" amalgam dental fillings that cause much disability (I'm a victim). Yet it is attempting to curtail sales of compounded substances that are often less toxic and/or composed of more natural substances many prefer. WHY?

When I recently tried to renew my prescriptions for compounded injectable nutrients, I was told they were no longer available, because the FDA had closed down the manufacturing company, apparently without any concern or provision for those depending on their products. WHY??

Then I learned that the FDA's proposed MOU (ref 3) would make it almost impossible for me to get the injectable nutrients I depend on to maintain any quality of life, since they are compounded out of state. WHY???

The reason I am forced to depend on injectable nutrients is because I became very ill after a dentist let me swallow all the ground mercury following an extensive bite adjustment on 15 large mercury amalgam fillings. The mercury damaged my gut's ability to absorb nutrients. Yet the FDA has not removed mercury from dentristry or classified it as the poison it is. WHY????

I believe the FDA is the tool of medical and dental monopolies, and is being used by them to try to force competition out of business. They've long harrassed alternative health practioners and mercury-free dentists, and now are apparently after compounding pharmacies.

It's long past time to take steps to curtail the FDA's blatant abuse of power. Why not restructure it into an underwriter's laboratory similar to that of the electrical industry? This would take the politics out, and put TRUESAFETY IN.

Meanwhile, the FDA's Modernization Act of 1997 Section 503A and the MOU MUST BE AMENDED, so that it won't restrict physicians and consumers from obtaining products of their choice, and so it won't infringe on the rights of compounding pharmacists to serve the public's medical needs.

Distribution:FDA, U.S. Senators and Congressmen and Pres. Clinton

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Food & Drug Administration
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Re: Docket No. 98N-1265
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